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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,106	10/15/1999	Joseph R. Bertino	04983.0119.U	3645

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EXAMINER
KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	25

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/421,106	BYRUM, JOSEPH R.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,16 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,16 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action responds the Amendment received on December 19, 2002 (Paper No. 24).

Specification

The objection to the specification for failing to comply with the Sequence Rules set forth in 37 CFR 1.821 through 1.825, made in the Office Action mailed on September 20, 2002, has been withdrawn in view of the Amendment received on December 19, 2002, complying with the rules.

Claim Rejections - 35 USC § 112

The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on September 20, 2002, has been withdrawn in view of the Amendment received on December 19, 2002, amending the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 1-9 and 16 (and the newly filed claims 19-24) because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, made in the Office Action mailed on September 20, 2002, is maintained for the reasons of record.

Applicants' argument received on December 19, 2002 have been fully considered but they are not found persuasive. Applicants' arguments will be addressed in the order they were presented.

Applicants state that the Examiner acknowledged that Applicant has disclosed several utilities for the nucleic acid molecules of the present invention, for example, to detect presence or absence of polymorphisms, as probes for expression profiling, or as tools for screening possible herbicide compounds (page 5), but concluded that that none of the utilities disclosed in the present application satisfy 35 U.S.C. 101 because the nucleic acids as disclosed, do not provide to one ordinarily skilled in the art, what the presence or absence of the claimed nucleic acids would be useful for.

Applicants then cite *Brenner v. Manson*, 383, U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966) in stating that the benefit derived by the public from an invention should be substantial (paraphrased). Such benefit is defined as having a "real world" or substantial benefit.

The question is whether the claimed nucleic acids can be useful as probes, not by their inherent property of being able to hybridize to their complement, for all nucleic acids can specifically hybridize to their complements, but whether or not the result of the hybridization gives a "real world" or immediately apparent utility to a skilled practitioner in the art. The answer to that question, based on the Applicants' disclosure is "no."

The only description provided by the Applicants' specification is what a nucleic acid could be useful for based on their inherent property. A nucleic acid, by its inherent property, hybridizes to its complement. Therefore, such nucleic acid "could be" used in any assay involving hybridization. Such assays are described in the Applicants' disclosure, *i.e.*, identifying

polymorphism, probes for expression profiling, or as a tool for screening possible herbicide compounds (Brief, page 6). However, the specification does not give any information as to what knowledge a skilled practitioner is able to "glean," from the result of such assays. The only conclusion the skilled practitioner is able to come to is the fact that the nucleic acid was present in a sample. No other information is taught or suggested by the Applicants. In other words, the specification does not provide any immediately apparent utility resulting from the detection of the nucleic acid. After such detection, the skilled artisan must conduct "further research" in order to be able to conclude its immediately apparent utility. If the nucleic acid was to be used in detecting the presence of polymorphisms, an example of immediately apparent utility would be, a diagnostic marker for plant trait. If the nucleic acid was to be used as a primer, an example of an immediately apparent utility would be amplifying a region of the plant gene suspected of harboring certain plant traits. If the nucleic acid was to used to detect differential expression, an example of an immediately apparent utility would be in knowing that differential expression of a specific nucleic acid in plants is indicative of certain plant trait or disease. Such information would give a conclusive, immediately utility to a skilled artisan in using the nucleic acid. In other words, the skilled artisan would know what benefit would be gleaned from that particular nucleic acid in a particular assay.

However, the specification provides no such information. The specification only provides a starting point for the skilled practitioner to conduct further research to conclusively arrive at such immediately apparent utility.

For example, Applicants contend that the nucleic acids of the present invention can be used in detecting polymorphisms. However, the specification does not disclose a single

polymorphism found in any of the nucleic acids. It is a speculative utility. Applicants have not provide any evidence that such polymorphisms even exist. Secondly, Applicants contend that the nucleic acid of the present invention could be useful in screening for possible herbicide. However, the specification contains no information in which nucleic acid provides resistance to any of the herbicides. It is again a speculation without any evidence or guidance. The skilled artisan, at best, would have to use each of the nucleic acids in an assay involving herbicide to determine which of the nucleic acids are (if any are) useful against herbicides, all of which requires further experimentation. The fact that such experimentation is needed fully demonstrates that the claimed nucleic acids and the specification of the instant application has not conclusively arrived at an immediately apparent utility as courts have expressed.

Applicants also state that Examiner maintains that Applicants has not given any immediately apparent benefit, substantial or real-world utility for the claimed nucleic acids simply because any other molecules can be used for the same purposes (*i.e., probes, markers, etc.)*. Applicants continue to state that such determination is wrong as a matter of law – there is no requirement of exclusive utility in the patent law (page 7).

The claimed nucleic acids were not rejected as lacking substantial utility just because any nucleic acids can be used as probes or markers *per se*. Contrary to Applicants' misunderstanding, the Office issues many probe patents when such probe has been shown to have an immediately apparent utility. The nucleic acids of the present application does not have such utility as reasons set forth above. The statement which Applicants were referring to was meant to express that if Applicants' arguments were accepted, any piece nucleic acid isolated

from anything would be patented without any additional information, since all nucleic acids "can be" at least be used (not "would be") as a probe.

Applicants argue that the nucleic acid of the present invention would provide better starting point for isolating plant promoter sequences than a random nucleic acid. This is only because the present nucleic acids were derived from plants. Since the nucleic acid was derived from a plant, it is an obvious fact that such nucleic acid would provide better hybridization. If such argument is valid, then any nucleic acid isolated from a mammal would have patentable utility because such nucleic acid would provide a better starting point for isolating animal promoter sequence than a plant sequence. Additionally, the specification does not disclose the distance or direction one has to walk on a chromosome from the corresponding location to reach the corresponding promoter. Thus, starting the walk at the corresponding chromosomal location is no more help in identifying the promoter than is picking a specific location in a haystack to start looking for a needle when one does not know where the needle is relative to the starting location. Initiation of a chromosome walk at the corresponding chromosomal location is considered non-specific because any EST would serve the purpose for isolating an uncharacterized promoter, since any chromosomal location is expected to be linked to a promoter. The specification fails to disclose sufficient characteristics of the corresponding promoter, such as its sequence or precise location relative to the genomic location corresponding to the claimed nucleic acid molecule, to inform one of what the corresponding promoter is or when it has been isolated. For example, a nucleotide sequence is identified during the chromosome walk as a putative promoter by sequence analysis, is then subcloned into operable linkage with a reporter gene and transfected into an appropriate cell, but found not to express the

reporter gene in the cells. This result could mean the putative promoter: is not truly a promoter, i.e. a false positive; is not the corresponding promoter; or is incomplete, i.e. lacked additional sequence elements required for promoter activity in the seed pod cells. Substantial utility means that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate* benefit to the public." *Nelson v. Bowler*, 206 USPQ2d 881, 883 (CCPA 1980) (emphasis added). Since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one skilled in the art that it has been isolated, there can be no "*immediate* benefit to the public" in using the claimed nucleic acid molecule in this capacity; "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner* at page 696.

Therefore, the specification of the instant application lacks disclosure for a skilled practitioner to conclusively realize an immediately applicable utility for the claimed nucleic acids as discussed above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-9 and 16 (and the newly filed claims 19-24) under 35 U.S.C. 112, first paragraph, because the claimed invention is not supported by either a specific and/or substantial utility or a well established utility for the reasons set forth above one skilled in the art would not know how to use the claimed

invention, made in the Office Action mailed on September 20, 2002, is maintained for the reasons of record.

Applicants' arguments received on December 19, 2002 have been fully considered but they are not found persuasive for the reasons stated above.

Preliminarily, claim 8 and its dependent claims 9 and 16 are drawn to a vector comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO: 1-10. Because it is not explicit whether the vector comprises a nucleic acid sequence "consisting" or "comprising" the SEQ ID Numbers, the latter interpretation (open language) has been assumed for the purpose of prosecution.

The rejection of claims 1-9 and 16 (and the newly filed claims 19-24) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the invention was filed, had possession of the claimed invention, made in the Office Action mailed on September 20, 2002, is maintained for the reasons of record.

Applicants' arguments received on December 19, 2002 have been fully considered but they are not found persuasive for the reasons of record.

The issue is whether Applicants were in possession of the genus being claimed. This genus is not restricted to any particular disclosed subgenus or species, such as vectors comprising the SEQ ID Numbers as an insert. The only nucleic acid molecule described by complete structure is that which consists of SEQ ID Numbers 1-10. The only nucleic acid molecule comprising SEQ ID Number described in the specification by other characteristics are

generic vectors comprising SEQ ID Numbers 1-10. While it is acknowledged that Applicants need not describe "every nuance" of the claimed invention, the written description must bear a reasonable correlation to that which is claimed. The disclosed subgenus and species embraced by the claims are not representative of the entire genus being claimed. The genus of nucleic acid molecules being claimed embraces any and every type of nucleic acid molecule that hybridizes to and/or comprises SEQ ID Numbers 1-10, and additional sequences of any size and sequence, **not just** vector backbones. Clearly, at the time of filing, Applicants were not in possession of genomic materials that contain the common EST fragment, **which are embraced by the open-ended language** of the claims. The specification does not disclose what characteristics these additional sequences may or may not have that are consistent with the operability of the nucleic acid molecules as probes or primers for detection of SEQ ID Numbers 1-10 in a target sequence, and all disclosed uses for the claimed nucleic acid molecules are fundamentally as probes or primers, at least in some aspect. The specification does not disclose encoding sequences or open reading frames (ORFs).

With respect to full length mRNAs, cDNAs and genomic sequences, one skilled in the art would reasonably conclude that the claims embrace these nucleic acid molecules, and the specification provides no physical (i.e. structural) characteristics of these molecules to distinguish them from other nucleic acid molecules comprising SEQ ID Number 1 and no other indication that would suggest Appellant possessed them. This particular subgenus embraced by the claims has a disclosed potential utility not possessed by those members of the claimed genus useful only in hybridization. Full length mRNAs, cDNAs and genomic sequences (genes) would encode the corresponding protein(s).

A fundamental issue here is specific to the very narrow class of product that is nucleic acid molecules. The basic question upon which Applicants and the Examiner disagree is whether the disclosure of a partial sequence of otherwise uncharacterized nucleic acid molecules that may encode a corresponding protein is sufficient to establish possession of a broad genus based solely on the description of the partial sequence, where the broad genus embraces the uncharacterized nucleic acid molecules by default. The subgenus of uncharacterized nucleic acid molecules that encode any corresponding protein is explicitly alluded to in the specification, and disclosed as possessing an additional use *not* possessed by any other members of the broad genus being claimed, i.e. encoding the protein. The specification fails to provide any structural or functional characteristic for these desired nucleic acid molecules, which encode the protein, that would distinguish them from the other members of the genus, which simply hybridize and/or comprise SEQ ID Numbers 1-10 as the sole distinguishing feature. As stated in *University of California v. Eli Lilly and Co.* at page 1404:

An adequate written description of a DNA ... "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

That Applicants' claims embrace nucleic acid molecules that encode a corresponding protein, whatever it may be, is clearly evident from the claim language chosen. The Court in *University of California v. Eli Lilly and Co.*, at page 1405, further noted regarding generic claims:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe* , 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . .").

In the instant case, the only species specifically enumerated are the nucleic acid molecules of SEQ ID Numbers 1-10. The specific embodiments that in addition to SEQ ID Numbers 1-10 include nucleic acids that will allow the corresponding protein to be encoded cannot be predicted without the coding sequence itself. This coding sequence has not been disclosed. Clearly, the specification would not show one skilled in the art that these desired subcombinations were possessed by Applicants, and thus the embracing genus was also not possessed.

Therefore, for the foregoing reasons, the claims lack written description as required under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Laten et al. (SEQ ID NO: 8), made in the Office Action mailed on September 20, 2002 is withdrawn in view of the Amendment received on December 19, 2002, amending the claim.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-

3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

2/25/03

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
2/26/03